REMARKS/ARGUMENTS

Claims 15-24 are active.

Claims 15-24 find support in original claim 1-14 and the specification at page 1, lines 15-18; page 4, lines 15-16; page 4, lines 18-18; page 4, lines 19-21 and the Examples.

No new matter is added.

The claims of this application are directed to a method for the chromatographic and quantitative analysis of proteins in which a poloxamer surfactant is added to the protein solution. That method as defined in Claim 15 includes three steps:

preparing the protein sample by adding a poloxamer to the sample;

performing chromatography on the protein sample; and

manipulating data to determine the quantity of the protein, wherein the quantity of the protein is determined using data from calibration with a standard

As discussed in the specification on pages 3 and 4 the addition of the poloxamer surfactant avoids protein loss and does not interfere with analysis in determining purity and concentration. The examples of this application provide a number of statistical analyses demonstrating that this is the case.

The Action to which the present paper responds, raised a series of obviousness rejections. The primary two references in these rejections are the Miksik publication in the Journal of Chromatography and the Caldwell patent (US 5,516,703). The Miksik publication describes adding pluronic F127 (see page 110, column 2) for the chromatographic separation of collagen type fragments. The Examiner combines this disclosure with Caldwell who teaches the benefits of poloxamer surfactants for coating hydrophobic surfaces.

The remaining rejections citing other publications are to allege that certain features of the dependent claims would have also been obvious. However, the core issue rests on the combination of Miksik and Caldwell.

Applicants submit that none of the cited documents describe the claimed quantitative method where the quantity of the protein is assessed after chromatography as defined in the claims. At page 4 of the Action, it is alleged that Miksik teaches detecting the quantity and purity of the protein. However, FIG 1B of Miksik identifies individual fractions of collagen peptides but does not determine the protein quantity sing data from a standard calibration.

Further, none of the cited documents describes the beneficial effect of poloxamer in quantitative analyses as shown in the specification in Example 1 at page 12, lines 12-15 where the protein FSH can be quantified separately from its free subunits which are to be considered degradation products. Also, in Example 2 at page 19, lines 17-18 that "this is a substantial improvement over samples prepared without Pluonic F68."

Reconsideration and withdrawal of the rejection based on Miksik and Caldwell is requested.

As noted above, the remaining rejections cite to various documents to allege that certain features of the dependent claims would have been obvious. Specifically, Lee is cited for the purpose of size-exclusion chromatograph, Wen is cited for SCF and size exclusion chromatograph, Wu is cited for FSH and size exclusion chromatography, Arduini is cited for IFN beta-1a and size exclusion, and Toschi and Ek-Rylander are cited for concentrations of Pluronic F68 and other buffer related disclosure. However, Miksik and Caldwell do not describe the claimed quantitative method where the quantity of the protein is assessed after chromatography as defined in the claims, neither do any of the subordinate citations combined with Miksik and Caldwell, and as such the combination of these publications do not render what is claimed obvious.

Withdrawal of these rejections is requested.

Finally it is noted that this 371 application has a counterpart in Europe, EP1625147, which has been granted. A copy of the initial Examination report with cited publications is attached in an IDS.

Allowance of this case is requested.

Respectfully submitted,

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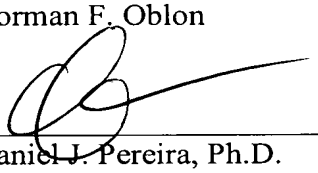

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